Stratton VA Medical Center
IRB Standard Operating Procedure
NON-VETERAN SUBJECTS

Please Note: This SOP does not apply to veteran research subjects. Veteran subjects who are not registered with the VA and do not wish to apply for VA services must, nevertheless, complete the full 10-10EZ form.

Non-veterans research subjects perform a vital role in the furtherance of VA research. The purpose of this SOP is to provide information on the special requirements regarding the participation of non-veteran subjects and to provide a streamlined approach to having non-veterans entered into the VA database.

One purpose of this procedure is to meet the progress note writing requirement for all consented research subjects (please see Consent SOP on the Stratton VA Research Website for progress note content requirements and entry procedures). In order to write a progress note on a non-veteran, they must first be entered into the VA patient database. Once the non-veteran is in the database, a Computerized Patient Record System (CPRS) record will be available for documentation of progress notes and a hard copy will be scanned and made available for copies of consent forms.

Use of the Electronic Medical Record CPRS (EMR)

2006 VHA HANDBOOK 1907.01 Section 15 (2) c states that "A separate, unique health record is created and maintained for every individual assessed or treated by VHA, as well as those receiving community or ancillary care at VHA expense." Therefore, any non-veteran research subject who through the process of the research is being "assessed or treated by VHA" will require a unique entry in the EMR. However, not all non-veterans participating in VA research will require a electronic medical record. For example, a unique EMR will not be required for non-veterans participating in anonymous surveys, or caregiver research (as long as the caregiver is not receiving counseling, assessment or treatment). However, someone involved in research for which a blood-draw is required, given the potential risk of harm in this method of data collection, or a clinical assessment and/or treatment (e.g. clinical trial of medication or IND/IDE) would need to have an electronic medical record created – and that would include all the accompanying steps required for setting up an electronic medical record (see "The Process" below). It is expected that there will be circumstances which require further review by the IRB to determine whether an EMR might be required. The following examples may provide some guidance:

EMR Required	*EMR Not Required*
- A protocol involving the drawing of blood	- Donating blood/saliva/tissue sample anonymously. - Use of anonymous questionnaires to gather epidemiological data.

- Complete questionnaires about clinical problems but not for the purposes of assessing diagnoses or providing treatment.

Please Note: Non-veterans may be entered into VA-approved research studies only when there are insufficient veterans available to complete the study. Before enrolling non-veteran subjects, approval must be obtained from the Medical Center Director. Approval is requested via a memorandum to the Director (00), through the ACOS/R&D (15).

The memorandum, addressed to the Director, is signed by the PI, the ACOS/R&D, the COS and the Director. In the memorandum, it is important to include the following information: a) requesting approval for recruiting both veteran and non-veteran participants; b) name of study; c) purpose of study; d) reason for recruiting non-veteran participants; and e) estimated number of non-veteran and veteran participants who will be recruited.

Issuance of VA Notice of Privacy Practices

Investigators must provide a copy of the Department of Veterans Affairs Notice of Privacy Practices to non-veterans as part of the consent process. The standard language in the HIPAA Authorization template states: "Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you." Non-veterans will not have received the Notice because they do not enroll through the Veteran's Service Center (VSC). The Notice may be found on the Links Page of the Stratton VA Research website, and is imbedded as an electronic attachment, below.

Adobe Acrobat 7.0 Document

Secondary Subjects:

This applies to non-veterans human subjects. The process for entering them into the VA database must be followed if they have not been previously entered into the VA database. These individuals are referred to as secondary subjects when they have a relationship to the veteran and data may be collected from or about them that is specific to them as a subject. This data becomes part of the study involving the primary subject. If the data is used as part of an approved study that is completely separate from the study involving the veteran, then the issue does not involve a secondary subject because this individual would then be a primary subject in their own right. Regardless of the designation as secondary subject, secondary subjects become human subjects when they meet the DHHS or FDA definition of human subject:

DHHS: "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. Intervention includes both physical procedures by which data are gathered (for example,

venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject."

FDA: Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Under 21 CFR 812 this also includes an individual on whose specimen an investigational device is used. Family members, care givers, significant others and sexual partners are sometimes involved in research as secondary subjects. Family members and care givers may assist in study related activities and provide information about the subject without being considered subjects of the research, unless the data being collected is about themselves. When an individual with a relationship to a primary subject fills out a questionnaire about their personal responses to the questions, then they are secondary subjects. When a sexual partner of a primary subject provides an investigator with information, about their pregnancy status, the sexual partner is a secondary subject if the pregnancy information is to be used in research.

Need to Obtain Consent

When data is to be collected from or about a secondary subject, (as described above) consent must be obtained from the secondary subject (unless waived by the IRB). Data cannot be collected until after consent has been obtained.

Need to document as unique subject

Secondary subjects need to have documentation in the study file as unique subjects. They need to be listed on the consent log. All the documentation requirements described in the Consent SOP apply to secondary subjects.

Vulnerable Secondary Subjects

If the secondary subjects are part of vulnerable populations, the investigator must follow the provisions found in VHA Handbook 1200.5, Appendix D, Vulnerable Populations. Vulnerable populations as listed in the Federal regulations include: Pregnant women and fetuses; Prisoners; Mentally disabled and those with impaired decision-making capacity; Children; and Economically and educationally disadvantaged persons.

Veteran Research Regulations Apply To Non-Veterans

All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research. [VHA Handbook 1200.5, Requirements for The Protection Of Human Subjects In Research, 16. Participation of Non-Veterans as Research Subjects]

The Process

Data must be submitted to the VSC office in order to have a non-veteran entered into the VA patient database. The following 11 pieces of information are required:

1. Name
2. Gender
3. Social Security Number

4. Date of Birth
5. Address
6. Subject's signature
7. Status (Non-Veteran).

The following information will be requested on the 10-10 EZ form, but is not required for non-veteran research subjects:

1. Mother's Maiden Name
2. Place Of Birth
3. Mother's Full Name
4. Father's Full Name

As stated, the first seven (7) items listed above must be entered on a 10-10 EZ form. The data for items 1 through 7 is to be entered in Section I of the 10-10 EZ form. There is a box for each of the 7 items listed above. (Please see example below.) The subject must sign on page 3. The words **RESEARCH (NON-VETERAN SUBJECT)** is to be written in bold print at the upper margin of the 10-10 EZ form. The last 4 items listed above may be submitted on a separate sheet of paper or written in on available space on the 10-10 EZ form.

The 10-10 EZ form may be downloaded and printed from the Stratton VA Research website. The 10-10 EZ form is also available from the VSC office.

The 10-10 EZ form with the seven (7) items entered along with the last four (4) items (option) must be submitted to the VSC office for entry. The VSC office must be provided with **contact information for an individual on the staff of the research project** so that confirmation of entry into the VA database can be provided.

The VSC office will have the non-veteran subject's data entered into the system as a "**Research Subject**."

The VSC office will send an **encrypted e-mail message** to the contact person for the research project notifying him or her that the subject has been entered into the system. No PHI will be sent by regular e-mail.

The non-veteran subject's **CPRS** medical record will be available for progress note documentation once the non-veteran subject has been entered into the system.

A CPRS **progress note** must be entered following each episode of research consent using the CPRS progress note template title: Research Consent & Contact.

A hard copy of the consent form is to be provided to the medical record room for scanning into the subject's medical record. (The original signed consent form is maintained in the investigator's file.)

The extent of data gathered and recorded for the EMR will not be the same as that required for a patient who is receiving assessment or treatment at a VA facility, but not participating in research. For instance, part of the EMR includes a "problem list," which is used for recording known illness or diagnoses. A thorough listing of problems for non-veteran research participants will not always be required. However, a listing of any and all problems, which may in some way effect the health of the research subject in relation to the activities of the protocol, would need to

be entered. Details of the data to be recorded in the EMR, and the rationale for the inclusion or omission of data in the EMR must be clearly documented in the protocol and will then be reviewed by the IRB.

Related Information (hyperlinks to some information below):

10-10 EZ Form, Section I
CPRS documentation access and training for non-clinician research staff
2006 VHA HANDBOOK 1907.01 Health Information Management and Health Records

RESEARCH (NON-VETERAN SUBJECT)

OMB Approved No. 2900-0091
Estimated Burden Avg. 45 min.
Expiration Date: 6/30/2007

Department of Veterans Affairs

APPLICATION FOR HEALTH BENEFITS

SECTION I - GENERAL INFORMATION

Federal law provides criminal penalties, including a fine and/or imprisonment for up to 5 years, for concealing a material fact or making a materially false statement. (See 18 U.S.C. 1001)

1. VETERAN'S NAME *(Last, First, Middle Name)* — Veteran's Name–Enter Subject's Name
2. OTHER NAMES USED
3. MOTHER'S MAIDEN NAME — Mother's Maiden Name
4. GENDER ☐ MALE ☐ FEMALE — Gender

5. ARE YOU SPANISH, HISPANIC, OR LATINO? ☐ YES ☐ NO

6. WHAT IS YOUR RACE? *(You may check more than one.) (Information is required for statistical purposes only.)*
☐ AMERICAN INDIAN OR ALASKA NATIVE ☐ BLACK OR AFRICAN AMERICAN
☐ ASIAN ☐ WHITE ☐ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER

7. SOCIAL SECURITY NUMBER — Social Security #
9. DATE OF BIRTH *(mm/dd/yyyy)* — Date of Birth
10. RELIGION

8. CLAIM NUMBER
9A. PLACE OF BIRTH *(City and State)* — Place of Birth

11. PERMANENT ADDRESS *(Street)* — Address
11A. CITY — City
11B. STATE — State
11C. ZIP CODE — Zip Code

11D. COUNTY
11E. HOME TELEPHONE NUMBER *(Include area code)*
11F. E-MAIL ADDRESS

11G. CELLULAR TELEPHONE NUMBER *(Include area code)*
11H. PAGER NUMBER *(Include area code)*

12. TYPE OF BENEFIT(S) APPLIED FOR *(You may check more than one)*
☐ HEALTH SERVICES ☐ NURSING HOME ☐ DOMICILIARY ☐ DENTAL

13. IF APPLYING FOR HEALTH SERVICES OR ENROLLMENT, WHICH VA MEDICAL CENTER OR OUTPATIENT CLINIC DO YOU PREFER?

14. DO YOU WANT AN APPOINTMENT WITH A VA DOCTOR OR PROVIDER AS SOON AS ONE BECOMES AVAILABLE?
☐ YES ☐ NO I am only enrolling in case I need care in the future.

15. HAVE YOU BEEN SEEN AT A VA HEALTH CARE FACILITY?
☐ YES, LOCATION: ☐ NO

16. CURRENT MARITAL STATUS *(Check one)*
☐ MARRIED ☐ NEVER MARRIED ☐ SEPARATED ☐ WIDOWED ☐ DIVORCED ☐ UNKNOWN

17. NAME, ADDRESS AND RELATIONSHIP OF NEXT OF KIN
17A. NEXT OF KIN'S HOME TELEPHONE NUMBER *(Include area code)*
17B. NEXT OF KIN'S WORK TELEPHONE NUMBER *(Include area code)*

18. NAME, ADDRESS AND RELATIONSHIP OF EMERGENCY CONTACT
18A. EMERGENCY CONTACT'S HOME TELEPHONE NUMBER *(Include area code)*
18B. EMERGENCY CONTACT'S WORK TELEPHONE NUMBER *(Include area code)*

19. INDIVIDUAL TO RECEIVE POSSESSION OF YOUR PERSONAL PROPERTY LEFT ON PREMISES UNDER VA CONTROL AFTER YOUR DEPARTURE OR AT THE TIME OF DEATH. NOTE: THIS DOES NOT CONSTITUTE A WILL OR TRANSFER OF TITLE *(Check one)*
☐ EMERGENCY CONTACT ☐ NEXT OF KIN

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Electronic Research Clinic
CPRS will require a clinic appointment to apply the research progress note to. For those research studies that are not part of medical care, a research clinic will be selected in the computer as the location of the "clinic visit". This is not a physical clinic location but rather a clinic designated in the computer.

Encounter Codes
CPRS progress notes require encounter information (CPT Codes) related to procedures and diagnoses. All staff who will write progress notes need to attend training in Electronic Encounter documentation. Researchers also need to individually contact the VSC office to obtain the correct codes.